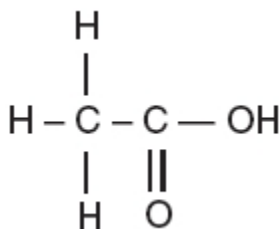


## **BOROFAIR - acetic acid solution/ drops**

Major Pharmaceuticals

### **DESCRIPTION**

Acetic Acid 2% in Aqueous Aluminum Acetate Otic Solution contains acetic acid 2% as the active ingredient, in a solution containing aluminum acetate (formed from Aluminum Sulfate, Calcium Carbonate, Glacial Acetic Acid), Boric Acid, Sodium Hydroxide and Purified Water. Sodium Hydroxide and/or Glacial Acetic Acid may be added to adjust the pH (3.5 to 5.0). Acetic Acid 2% in Aqueous Aluminum Acetate Otic Solution is instilled in the external auditory canal. Acetic acid is an astringent and antimicrobial agent. Chemically, acetic acid is C<sub>2</sub>H<sub>4</sub>O<sub>2</sub> and has the following structural formula:



Molecular weight: 60.05

### **CLINICAL PHARMACOLOGY**

Acetic acid is antibacterial and antifungal and is effective against microorganisms (bacteria and fungi) that infect the ears of patients with acute diffuse external otitis. *In vitro* tests, minimum lethal-time was less than 0.25 minutes when bacteria and fungi isolated from patients with otitis externa were exposed to 2% acetic acid. Quantitative absorption of acetic acid 2% from external auditory canal is not known.

### **INDICATIONS AND USAGE**

For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial.

### **CONTRAINDICATIONS**

Hypersensitivity to acetic acid or any of the ingredients in this product. Perforated tympanic membranes is considered a contraindication to the use of any external ear canal medication.

### **WARNINGS**

Avoid use or use with caution in patients with perforated tympanic membrane (See CONTRAINDICATIONS).

### **PRECAUTIONS**

#### **General**

Care should be taken to assure that the Acetic Acid 2% in Aqueous Aluminum Acetate Otic Solution gets into the ear canal and stays in contact with the affected area long enough for the drug to act.

Discontinue promptly if sensitization or irritation occurs.

#### **Carcinogenesis, mutagenesis, impairment of fertility**

No long term studies in animals have been performed to evaluate the carcinogenic potential of Acetic Acid 2% in Aqueous Aluminum Acetate Otic Solution.

### **ADVERSE REACTIONS**

Irritation may occur.

### **OVERDOSAGE**

No Toxic effect has been reported with overdosage of Acetic Acid 2% in Aqueous Aluminum Acetate Otic Solution.

### **DOSAGE AND ADMINISTRATION**

The patient should lie on the side with the affected ear uppermost. Instill 4 to 6 drops into the external auditory canal and maintain this position for 5 minutes. Repeat the procedure every 2 to 3 hours.

### **HOW SUPPLIED**

Acetic Acid 2% in Aqueous Aluminum Acetate Otic Solution is available in 60 mL plastic squeeze bottle with otic tip  
Prod. No. 06620.

**STORAGE**

Store between 15# - 30# C (59# - 86# F).

PROTECT FROM FREEZING

**DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.**

KEEP OUT OF REACH OF CHILDREN.

**MANUFACTURER INFORMATION**

**Bausch & Lomb Incorporated**

Tampa, FL 33637

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9066901

PRINCIPLE DISPLAY PANEL



60 mL

**Borofair Ear Solution**  
(Sterile)  
Acetic Acid 2% in  
Aqueous Aluminum  
Acetate Otic Solution

NDC 0904-3524-03

**Borofair Ear Solution**  
(Sterile)

Acetic Acid 2% in  
Aqueous Aluminum  
Acetate Otic Solution

**Contains:**

ACTIVE: Acetic Acid 2%;  
INACTIVES: Aluminum  
Acetate (formed from  
Aluminum Sulfate,  
Calcium Carbonate, Glacial  
Acetic Acid), Boric Acid,  
Sodium Hydroxide,  
Purified Water. Sodium  
Hydroxide and/or Glacial  
Acetic Acid may be added  
to adjust pH (3.5–5.0).

**KEEP OUT OF REACH  
OF CHILDREN.**

Manufactured by  
**Bausch & Lomb Incorporated**  
Tampa, Florida 33637

Distributed by  
**Major Pharmaceuticals**  
Livonia, MI 48150 USA



**FOR USE IN THE EARS ONLY.**

**NOT FOR USE IN THE EYES.**

Read enclosed package insert  
before using.

**USUAL DOSAGE:** Instill 4 to  
6 drops every 2 to 3 hours.

**STORAGE:** Store between  
15°–30°C (59°–86°F).  
PROTECT FROM FREEZING.

NDC 0904-3524-03

**Borofair  
Ear Solution**  
(Sterile)

**Acetic Acid 2%  
in Aqueous  
Aluminum Acetate  
Otic Solution**

**CAUTION: NOT FOR  
OPHTHALMIC USE**

**Rx only**

60 mL



**DO NOT USE IF IMPRINTED  
NECKBAND IS NOT INTACT.**



**MAJOR®**  
PHARMACEUTICALS



4  
006145  
07/04

XQ70955  
R.5/04-72  
CT06620



**FOR USE IN THE EARS ONLY.  
NOT FOR USE IN THE EYES.  
USUAL DOSAGE:**  
See Package Insert.

**STORAGE:** Store between  
15°–30°C (59°–86°F).  
**PROTECT FROM FREEZING.**

Mfd. by  
**Bausch & Lomb Incorporated**  
Tampa, Florida 33637

XE42182 R.5/04-72 CT06620

NDC 0904-3524-03

## **Borofair Ear Solution (Sterile)**

**Acetic Acid 2% in Aqueous  
Aluminum Acetate Otic Solution**

**CAUTION: NOT FOR OPHTHALMIC USE**

**Rx only**

**60 mL**

**MAJOR®**  
PHARMACEUTICALS



**EACH mL CONTAINS:** ACTIVE:  
Acetic Acid 2%; INACTIVES:  
Aluminum Acetate (formed from  
Aluminum Sulfate, Calcium  
Carbonate, Glacial Acetic Acid),  
Boric Acid, Sodium Hydroxide,  
Purified Water. Sodium Hydrox-  
ide and/or Glacial Acetic Acid may  
be added to adjust pH (3.5 – 5.0).

**DO NOT USE IF IMPRINTED  
NECKBAND IS NOT INTACT.**

**KEEP OUT OF REACH  
OF CHILDREN.**

Distributed by  
**Major Pharmaceuticals**  
Livonia, MI 48150 USA

